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April 7, 2004

Docket No. 03-080-1  
Regulatory Analysis and Development  
PPD, APHIS, Station 3C71  
4700 River Road, Unit 118  
Riverdale, MD 20737-1238

To Whom It May Concern:

Comments referring to Docket Number 03-080-1

**Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of  
Commodities**

The North Dakota Department of Agriculture and the State Board of Animal Health appreciate the opportunity to comment on these proposed rules. This is an issue that has many repercussions, and we feel that it is very important for the final rule to allow the importation of live animals and animal products from minimal risk areas while protecting the livestock industries and citizens of this country.

The North Dakota State Board of Animal Health and the North Dakota Department of Agriculture have previously submitted comments on this proposed rule. We continue to stand behind the comments previously submitted and would like to submit additional comments.

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## **General Comments:**

### Surveillance

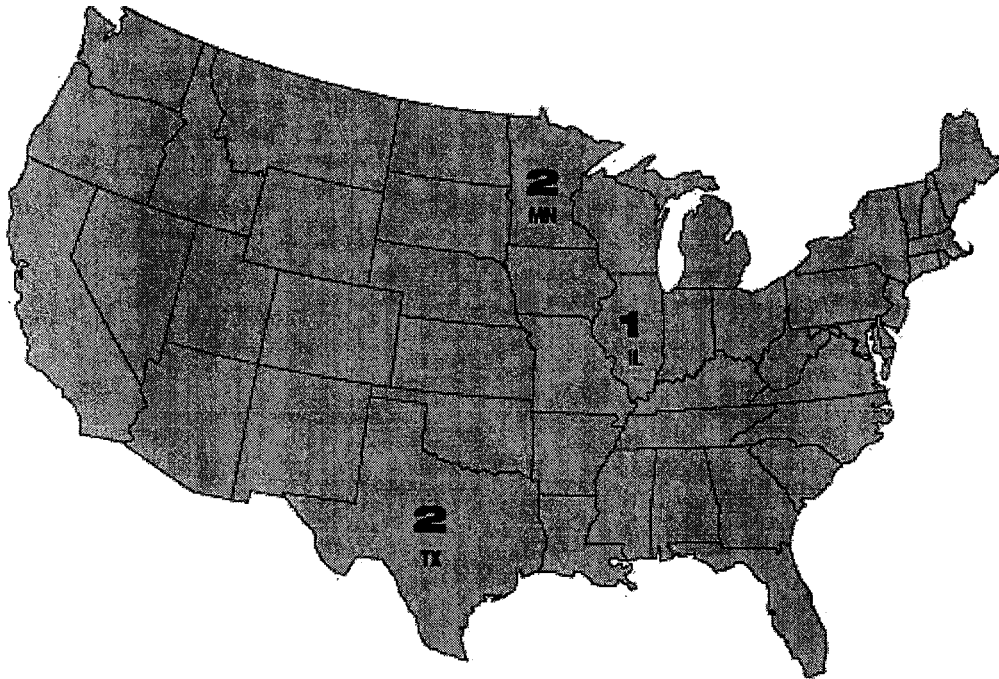
USDA has recently announced increased surveillance for BSE. The goal is to achieve surveillance on 201,000 to 268,500 cattle samples in the next 12-18 months. In contrast, according to the "Explanatory Note - Risk Analysis from Importation of Designated Ruminants and Ruminant Products from Canada into the United States, APHIS, February 2004" that was published with the most recent notice of the proposed rule "CFIA [Canadian Food Inspection Agency] plans to test a minimum of 8,000 animals over the next 12 months, and will continue to increase that number progressively. The ultimate number of animals tested will reflect the international standards existing at the time. These are expected to be revised over the next one to two years." Doing surveillance on 8,000 samples is adequate for detection of the disease, but surveillance on 8,000 samples is not adequate to establish the prevalence of the disease in Canada. Information on the prevalence of a disease in a country is critical to understanding the risk of importing the disease into this country and, thus, recognition of a country as "minimal risk" should be based on the established prevalence of the disease in a particular country. We do not feel that "minimal risk" status should be applied until the prevalence of the disease has been established.

### Surveillance on "High Risk" Animals:

Until recently USDA's definition of high risk animals included animals imported from a BSE affected country. USDA's own website that discusses BSE surveillance says, "APHIS has a surveillance program in place in the United States to ensure detection and swift response in the event that an introduction of BSE were to occur. **This surveillance program incorporates both the location of imports from countries known to have BSE** and targeted active and passive surveillance for either BSE or other form of TSE in cattle (emphasis added)." We do not believe that the BSE investigation is complete because of the failure to locate imports from a country known to have BSE.

There simply has not been enough of a traceback, epidemiologic investigation or surveillance done to say whether this is a North American problem or a Canadian problem and USDA should follow through with a traceback of Canadian imports. A traceback of Canadian imports in the United States would assist Canada in establishing the prevalence of the disease in that country and it would assure our trading partners of the safety of the U.S. beef supply. The closely related age and geographic location of the two BSE positive Canadian animals may indicate a potential regional problem during the 1996 to 1997 timeframe.

## **Status of Cattle Imported Into the US. From Other European Countries in 1996-97 (as of October 18, 2002)**



The above figure was downloaded from USDA's current BSE website to illustrate the emphasis that USDA has placed on imports from BSE affected countries prior to the Canadian BSE case.

At first glance a traceback of Canadian imports appears to be a difficult task. However, if a traceback of Canadian imports was focused on potential cohorts of the infected Canadian animals far fewer animals would need to be found. If cohort animals [i.e. animals born between April 1, 1996 and April 1, 1998 (according to OIE standards) that originated in Alberta or Saskatchewan (the origin of the 2 BSE cases)] were selected for identification and surveillance, we could determine if there is a Canadian BSE problem and at the same time protect the health of the US cattle population by removing potentially infected high risk animals. As an example, by reviewing international health certificates on file, North Dakota has identified Canadian animals imported into the state in the last ten years that fit the cohort definition. North Dakota has identified 258 cattle on 77 premises that would fit the definition of cohorts of the infected animals. It is likely that North Dakota has a higher than average number of Canadian breeding cattle within its borders compared to other states. A traceback with testing of these animals does

not appear to be insurmountable. A large number of these animals have probably already been slaughtered. Looking just for these "animals of interest" would seem to be the minimum we should do. We would also suggest that Canada should target their surveillance towards animals of this age and location as well.

BSE, a North American Problem?:

We are also concerned about the description of these two cases as a North American BSE problem. The US and Canadian industries are distinct and are subject to different regulations and levels of enforcement. The movement of cattle from the US into Canada is very difficult and subject to extensive testing. Thus, we do not have an integrated industry. We do have a US industry that has incorporated many Canadian animals into it and this has now placed the US industry at risk. It also suggests that a significant level of increased US testing should be targeted at Canadian imports as described above.

The International Team of BSE Experts said, "However, it is probable that other infected animals have been imported from Canada and possibly from Europe. These animals have not been detected and therefore infective material has likely been rendered, fed to cattle, and amplified within the cattle population, so that cattle in the USA have also been indigenously infected." This statement does not take into account the ruminant feed ban that has been in place in the US since August of 1997. Admittedly, the feed ban has not been perfectly enforced and there have been some loopholes, but, according to the Harvard Risk Assessment, it is adequate to control and eradicate the disease if the disease has been introduced into the country. Even if BSE infective material has been rendered, it would be very unlikely that it has been fed to cattle and it certainly has not been amplified within the cattle population.

The International Team of BSE Experts also said, "the subcommittee firmly believes that the first case of BSE in the United States can not be considered in isolation from the whole cattle production system in North America. The significance of this BSE case cannot be dismissed by considering it 'an imported case'. The first BSE case in the USA, and the first 'indigenous case' reported in Canada in 2003, must be recognized as both being BSE cases indigenous to North America. For this reason, close collaboration between all appropriate agencies in NAFTA is essential for proper management of North America's BSE problem." We disagree with this statement. There simply has not been enough of an epidemiological investigation or surveillance in either the US or Canada to state that BSE has become a "North American" problem. We encourage the USDA and CFIA to complete their epidemiologic investigations, including identifying animals in the US from BSE affected countries, and to do adequate surveillance in both countries to determine the prevalence of the disease before decisions are made regarding the relative risk associated with importing animals from a BSE affected country.

We encourage USDA to identify cohorts of the infected Canadian animals and to do adequate surveillance of these animals to identify their relative risk. The very words of the International Review Team, when they say, "However, it is probable that other infected animals have been imported from Canada and possibly from Europe." indicates that they believe the Canadian imports are potentially infected. We do not see the "will" within USDA to identify and conduct surveillance on Canadian imported cattle and it appears that USDA is content to have the US considered a BSE affected country.

#### Exposure to Ruminant Protein:

The assumption is being made that exposure to ruminant protein occurred prior to the initiation of the ruminant feed ban. It is very possible that ruminant protein was available in milk replacers or other ruminant feed that may have been fed to the two BSE infected animals prior to August 1997. However, it is just as probable that ruminant protein may have been fed after the feed ban went into affect due to the feeding of poultry or swine feed to cattle on farms where multiple species were raised. There is no enforcement of the feed ban on farms and a potential leak in the feed ban exists at this level. Therefore, we support the removal of all SRM from human food and animal feed.

The potential exposure of animals before they are 30 months of age means that infected animals may be entering the US food supply prior to developing the disease. Even if the prion is present at undetectable levels, it would, nevertheless, be present and if SRM were removed and allowed to be rendered into animal feed the potential would exist for exposure of ruminants to the BSE prion.

#### Country of Origin Labeling

If the US is going to import beef and beef products from BSE affected countries, Country of Origin Labeling (COOL) should be established to protect consumer confidence in the US. COOL would at least provide consumers with the opportunity to select meat from countries which they perceive as safe. We strongly recommend that COOL first be fully implemented in the US so consumers would have more specific knowledge as to the origin of their beef. At least, in the event of another BSE case, consumers would then be able to differentiate meat products in the marketplace and may feel more confident in their beef purchases. This would arguably lead to a smaller decrease in expected demand for beef, which should serve to decrease the negative price impacts which would likely follow the discovery of another BSE case.

### Specific Comments

#### Removal of SRM:

We are specifically concerned about the statement in the recently published rule that says, "We now believe it would not be necessary to require that beef imported from BSE minimal-risk regions be derived only from cattle less than 30 months of age, provided equivalent measures are in place to ensure that SRM's are removed when the animals are slaughtered, and that such other measures as are necessary are in place."

There are many knowledge gaps with regard to BSE and all transmissible spongiform encephalopathies (TSE's) in general. Restricting the importation of beef to product derived from cattle less than 30 months of age would fit the mantra that has been repeated numerous times throughout the BSE investigation. It should be done "out of an abundance of caution."

#### Live Animals or Animal Products?

It is unclear from the proposed rule published in the Federal Register on March 8, 2004 if the proposed rule applies to live animals from minimal risk regions. The beginning of the "Summary" of the proposed rule says "We are reopening the comment period for our proposed rule that would amend the regulations regarding the importation of animals and animal products to recognize, and add Canada to, a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy into the United States via live ruminants and ruminant product." This implies that the new proposed rule would affect both live ruminants and ruminant products. However, at the end of the published proposed rule (near the end of page 10635), it is stated "With regard to the importation of live animals from BSE minimal-risk regions, APHIS is currently evaluating the appropriate approach regarding such animals and intends to address the issue in a supplemental rulemaking proposal in the Federal Register." This mixed message is confusing and we assume that APHIS intends that this rulemaking applies only to ruminant products and that a "supplemental rulemaking proposal in the Federal Register" will be initiated "with regard to the importation of live animals from BSE minimal-risk regions." However, this needs to be clarified.

In conclusion, we agree with the Harvard Risk Assessment which says that, even if a small number of cases enter the US, the disease will die out within twenty years. The real issue is: Can the US livestock industry survive the continued loss of consumer confidence and the continued loss of export markets that will occur with each additional "single" case of BSE if adequate surveillance has not been done to establish prevalence and the removal of high risk animals has not occurred? We strongly recommend that surveillance to determine the prevalence of the

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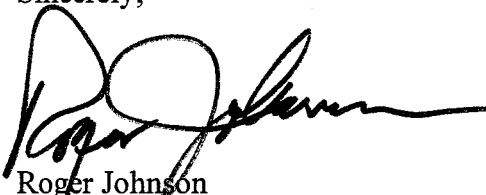
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disease in the US and in minimal risk regions be completed before minimal risk status is conferred on a region. Recognizing a region as a minimal risk region based on the assumption of low prevalence of disease is an extremely dangerous precedent to set.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Roger Johnson", with a stylized, flowing script.

Roger Johnson  
Agriculture Commissioner

A handwritten signature in black ink, appearing to read "Larry A. Schuler", with a stylized, flowing script.

Larry A. Schuler, DVM  
State Veterinarian

RJ:LS:tc